

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION**

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

**CASE NOS. 5:15CV57-RLV;
3:15CV211-RLV**

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

**PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT
BOSTON SCIENTIFIC'S COUNTER DEPOSITION DESIGNATIONS OF
EVAN BRASINGTON TAKEN 8/22-23, 2013**

BSC Counter Designation	Objection	Plaintiffs Counter Designation to BSC Counter Designation
<p>eb082213, (Page 73:3 to 73:15) 73</p> <p>3 Q. But Boston Scientific chose not to get that 4 experience prior to having it cleared and launching it. 5 Correct? 6 MR. ANIELAK: Form. 7 A. I would expect -- and I'm going from my 8 experience in what products I've launched -- they go 9 through a 510(k) process, that they must go through a 10 rigorous process, if it's not requiring a clinical 11 trial, to look at the clinical data that is available 12 and submit that to the FDA as a predicate device.</p>	<p>73:3-15 FRE 401, 402, 403 FDA</p>	

<p>13 If the FDA says this is not -- it does not 14 meet 15 that requirement, then they will require a clinical trial.</p>		
<p>eb082313, (Pages 400:5 to 401:18) 400</p> <p>5 Q. And then it looks like you moved over to be 6 vice president of worldwide marketing for the urology 7 franchise. Tell the jury what that means. What did you 8 do there? 9 A. So at that time the company made a decision as 10 we're entering the women's health space to split the 11 marketing role into two different areas. 12 And I was the vice president of marketing for 13 the urology products, and my responsibility was for all 14 of our stone management products. And these are people 15 that end up getting kidney stones or stones in their 16 ureter or their bladder. And we make products that 17 extract those stones from the body. There's about 18 approximately 2,600 product codes in this area. They're 19 products such as dilatation balloons, ureteral stents, 20 guidewires, sheaths, catheters, and so on. 21 And in addition to that, I was responsible for 22 the prostate. So we had products for BPH, a laser 23 technology, and also the Prolieve technology, which is 24 the microwave technology.</p> <p>401</p> <p>1 So the urology business represented 70 percent 2 of the company's revenue worldwide. 3 Q. So during this period of time from 2000 to 4 2005, you were on the urology side of the business and</p>	<p>400:5 – 401:18 FRE 401, 402, 403</p>	

<p>5 not the women's health side of the business. Is that</p> <p>6 right?</p> <p>7 A. Yes. My whole responsibility was on the</p> <p>8 urology side.</p> <p>9 Q. During this period of time from 2000 to</p> <p>10 2005,</p> <p>11 that's when the Advantage -- Boston</p> <p>Scientific's</p> <p>12 Advantage sling underwent its research and</p> <p>development</p> <p>13 process. Is that right?</p> <p>14 A. That's correct.</p> <p>15 Q. And were you working on that side of</p> <p>the</p> <p>16 business when the research and development</p> <p>was done on</p> <p>17 the Advantage sling?</p> <p>18 A. No. I was solely responsible for the</p> <p>urology</p> <p>product line.</p>		
<p>eb082313, (Pages 407:3 to 409:4)</p> <p>407</p> <p>3 Q. I want to talk a little bit about what</p> <p>4 marketing does. Describe generally what the</p> <p>marketing</p> <p>5 department does. Give the jury some sense of</p> <p>some of</p> <p>6 the big responsibilities of marketing.</p> <p>7 A. I actually get this question a lot, what's</p> <p>the</p> <p>8 difference -- what do you do in marketing</p> <p>exactly. And</p> <p>9 I always start with the clinical unmet needs</p> <p>because</p> <p>10 that's where marketing does start. And that's</p> <p>11 uncovering what the clinical unmet needs in</p> <p>the</p> <p>12 marketplace. We do that through interaction</p> <p>with</p> <p>13 physicians, conducting market research, voice</p> <p>of the</p> <p>14 customer, some voice of the patient, voice to</p> <p>the</p> <p>15 hospital, to collect that information.</p> <p>16 But mainly when you think of marketing</p> <p>and you</p> <p>17 think of product development, we're getting</p> <p>the</p> <p>18 information on what are the clinical unmet</p> <p>needs of the</p>		<p>[Counter Designations to</p> <p>407:3-409:4]</p> <p><i>eb082213, (Page 201:5 to</i></p> <p><i>201:10)</i></p> <p>201</p> <p>5 Q. Okay. Let's talk about</p> <p>Dr. Roger Goldberg.</p> <p>6 What did he develop?</p> <p>7 A. So Roger Goldberg -</p> <p>- again, to get the more</p> <p>8 accurate details, I think I</p> <p>would talk to Jeff Mann or</p> <p>9 Vance Brown, because</p> <p>those are the IP attorneys that</p> <p>are</p> <p>10 on there.</p> <p><i>eb082213, (Page 201:15 to</i></p> <p><i>201:16)</i></p> <p>201</p> <p>15 Q. And his inventions</p> <p>resulted in what product?</p> <p>16 A. Uphold.</p> <p><i>eb082213, (Pages 203:12 to</i></p> <p><i>204:22)</i></p> <p>203</p> <p>12 Q. Okay. But my</p> <p>question is: With regard to the</p>

<p>19 products. And then once we establish that, we then</p> <p>20 determine if a product can be made to address that</p> <p>21 clinical unmet need.</p> <p>22 Q. And then does marketing work with outside</p> <p>23 physicians?</p> <p>24 A. Yes, we do.</p> <p style="text-align: center;">408</p> <p>1 Q. In what capacity?</p> <p>2 A. So with physicians outside or physicians in the</p> <p>3 marketplace, we establish relationships with some key</p> <p>4 opinion leaders or thought leaders that are considered</p> <p>5 experts or strong in some areas. We also have regional</p> <p>6 thought leaders for specific regions of the country.</p> <p>7 We also have some community-based physicians</p> <p>8 that we interact with and contract with, and then also</p> <p>9 fellows and our residents for a goal of trying to get a</p> <p>10 broad perspective of the marketplace.</p> <p>11 Q. And how do you use those doctors? Why are they</p> <p>12 a resource to the company? What are you using them for?</p> <p>13 A. Well, the number-one reason is uncovering a</p> <p>14 clinical unmet need and understanding what their</p> <p>15 challenges are in their practice, with their patients,</p> <p>16 with their outcomes, and hopefully coming up with</p> <p>17 resolutions to that.</p> <p>18 We also work with docs that come to us with</p> <p>19 specific ideas. We say no to many; we say yes to some.</p> <p>20 It's typically the ones that we say yes to are the ones</p> <p>21 that have a clinical -- I mean they have a patent and it</p> <p>22 truly addresses a clinical unmet need.</p> <p>23 And we also work with physicians from a</p>	<p>13 actual Uphold product, the only clinical data you had</p> <p>14 with regard to the Uphold product itself came from</p> <p>15 Dr. Goldberg, who was receiving a royalty on the</p> <p>16 product. True?</p> <p>17 A. I don't know. I would ask Janice Connor.</p> <p>18 Q. Okay. If that is the case, doesn't that</p> <p>19 present a conflict of interest?</p> <p>20 MR. ANIELAK: Form.</p> <p>21 A. I'm not an expert on contracting. My</p> <p>22 experience in the past is no, that's not a conflict of</p> <p>23 interest.</p> <p>24 Q. Well --</p> <p style="text-align: center;">204</p> <p>1 A. Because he invented the product.</p> <p>2 Q. Right. But he's also the one that's saying</p> <p>3 it's good and he's also the one that's getting paid. So</p> <p>4 doesn't Dr. Goldberg have a vested interest in saying</p> <p>5 that his product works well because if it works well,</p> <p>6 Dr. Goldberg makes more money?</p> <p>7 A. Yeah. I mean, this is getting out of my area</p> <p>8 of expertise from the standpoint of exactly how</p> <p>9 they're paid.</p> <p>10 But my understanding with these guys and how</p> <p>11 they're paid is they're paid on the patent of the</p> <p>12 product. That's what they're paid. They're paid on the</p> <p>13 idea that they brought and invented to the marketplace.</p>
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<p>24 training standpoint because the physicians are the ones</p> <p style="text-align: center;">409</p> <p>1 that do the training. And they're the ones we count on</p> <p>2 to do the training in our preceptorships and our</p> <p>3 proctorships as well as working in our cadaver labs and</p> <p>4 so on.</p>		<p>14 Q. Okay. But do you understand how a conflict</p> <p>15 could arise because if a -- when you're looking at data,</p> <p>16 data can be interpreted many different ways. Correct?</p> <p>17 A. Sure.</p> <p>18 Q. Isn't it possible that someone who has a</p> <p>19 financial interest in interpreting data could skew the</p> <p>20 data to help their own financial gain? That's a</p> <p>21 possibility, isn't it?</p> <p>22 A. Absolutely can happen.</p> <p>eb082213, (Page 193:15 to 193:19)</p> <p style="text-align: center;">193</p> <p>15 Q. It says, "I played an active role in assessing,</p> <p>16 developing, and negotiating the Dennis Miller and</p> <p>17 Roger Goldberg new product/royalty contracts."</p> <p>18 Do you see that?</p> <p>19 A. Yeah. I was involved in both.</p>
<p>eb082313, (Pages 412:4 to 422:9)</p> <p style="text-align: center;">412</p> <p>4 Q. You referred a number of times to unmet needs.</p> <p>5 In terms of Boston Scientific's -- the Pinnacle and the</p> <p>6 Uphold devices that were marketed by Boston Scientific</p> <p>7 for pelvic organ prolapse, how did those products</p> <p>8 fulfill an unmet need?</p> <p>9 A. Well, at the time that we were looking at the</p> <p>10 market for pelvic organ prolapse there were other</p> <p>11 companies already on the market, J&J, AMS, Bard, and</p> <p>12 others. And one of the things that we heard through</p>	<p>412:4-413:6 FRE 801, 802</p>	

<p> 13 physicians when we were determining if we were going to 14 come to the market, what are the clinical unmet needs. 15 So the way the first-generation products that 16 were on the market that were offered by the companies I 17 mentioned were -- it's a trocar that's passed through 18 the buttocks. There's four different trocars. It's a 19 blind passage. So many of the physicians that we talked 20 to had stated is it possible to do this procedure 21 intravaginally so you're not having to do a blind pass 22 through the buttocks. 23 The other thing that physicians were stating 24 when we're talking about what can we do to improve </p> <p style="text-align: center;">413</p> <p> 1 products that are already on the market is improving the 2 actual stability of the actual mesh, meaning the current 3 devices were Level 2 support, which is sutured to the 4 sidewall. And the whole idea of Level 1 support is, 5 according to the physician feedback, we said 6 repositioning the organ back into its normal anatomy. </p> <p>***</p> <p> 6 Q. I want to turn to the next slide from your 7 presentation where you talk about physician education. 8 When you're talking about physician education, tell the 9 jury what that means. 10 A. Physician education, physician training, that's 11 also what it's called. First, it's something I'm very 12 passionate about from the day I started with Boston </p>		
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<p> 13 Scientific and looking at different ways that we should 14 train our physicians. From Day 1 I set a goal, how can 15 we do this differently than our competitors. We did 16 that successfully on the urology side and then we 17 certainly have had multiple iterations on the women's 18 health side. 19 We have various types that we've started with. 20 Preceptoring. Preceptoring is when physicians that want 21 to learn a product can go watch a physician. 22 Proctoring is when the actual physician, that's 23 the training physician, goes to the actual site of the 24 person that wants to be trained. 417 1 And then we had our cadaver lab training. 2 We started the Pelvic Floor Institute, which 3 was a framework of our approach to training for stress 4 urinary incontinence and pelvic organ prolapse, which 5 has multiple levels and is considered by many physicians 6 as the gold standard. 7 Q. Does Boston Scientific -- are you training 8 doctors and the marketing people training doctors or how 9 are doctors getting trained? 10 A. No. As I said, our job is to build a frame- 11 work. But we -- for example, with the Pelvic Floor 12 Institute or with our proctoring or preceptoring, our 13 doctors that are contracted do the training. Marketing 14 does not do the training. We facilitate the framework 15 to do the training. 16 Q. And in terms of the training on the pelvic </p>	<p> 417:2-419:1 FRE 401, 402, 403 </p>	
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<p>17 organ prolapse devices and the stress urinary 18 incontinence devices, who within your organization would 19 know the most details about Boston Scientific's training 20 programs? 21 A. Abby Fischer would be the person what has been 22 most integrally involved with that. 23 Q. You mentioned the Pelvic Floor Institute. Tell 24 the jury what the Pelvic Floor Institute is. 418 1 A. Well, the Pelvic Floor Institute was, -- again, 2 clinical unmet needs are one thing to do with 3 innovation. But from a physician training standpoint, I 4 think you have to look at the same things. 5 So we talked to many of our thought leaders and 6 key opinion leaders and said, look, how is physician 7 training working at other companies and other areas and 8 where can it be improved? 9 And so we hired a faculty that basically helped 10 us build out a strategy on how to improve that. And 11 that includes a didactic portion as well as a hands-on 12 cadaver portion. 13 There are also built into the Pelvic Floor 14 Institute information on all the DFUs. You can see 15 illustrations of the product being used, videos of the 16 products being used, scientific, basic science data. 17 You can sign up for the Pelvic Floor Institute on there. 18 And the whole goal is let's train physicians at 19 the best possible way so that -- with the goal of 20 improving the outcomes of our devices. 21 Q. Are those materials available on a website 22 where physicians have access to that? 23 A. Yes. To my understanding, we're the only</p>		
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<p>24 company that has a site that is offered on a website to</p> <p style="text-align: center;">419</p> <p>1 all physicians 24 hours every day.</p> <p>2 Q. The next slide, you talk about clinical data.</p> <p>3 When you're talking about successful products, what role</p> <p>4 does clinical data play?</p> <p>5 A. Clinical data is very important at having</p> <p>6 successful products.</p> <p>7 Q. And does Boston Scientific have clinical data</p> <p>8 supporting the safety and effectiveness of its stress</p> <p>9 urinary incontinence, its sling devices?</p> <p>10 A. Yes, we do.</p> <p>11 Q. And does Boston Scientific have clinical data</p> <p>12 to support the safety and effectiveness of its Pinnacle</p> <p>13 and Uphold devices?</p> <p>14 A. Yes, we do.</p> <p>15 Q. In terms of the details of the studies, are you</p> <p>16 the best person to talk about all of that information or</p> <p>17 should we ask somebody else?</p> <p>18 A. Janice Connor would be the person that is best</p> <p>19 versed on all the clinical trial data that we have</p> <p>20 accumulated.</p> <p>21 Q. Is marketing responsible for analyzing the</p> <p>22 clinical data regarding Boston Scientific's stress</p> <p>23 urinary incontinence and pelvic organ prolapse devices?</p> <p>24 A. No, it's not.</p> <p style="text-align: center;">420</p> <p>1 Q. Who would be analyzing that kind of</p> <p>2 information?</p> <p>3 A. Well, it would be under Janice's department.</p> <p>4 We have biostatisticians that fall in corporate</p> <p>5 clinical. It's not directly under Janice, but they're</p> <p>6 the ones that look at that data.</p> <p>7 Q. The next slide, you talk about KOL development.</p>	<p>419:7-14 FRE 403</p>	
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<p>8 What role does the KOL development play in having 9 successful products? 10 A. Again, just being in the medical-device market 11 for almost 28 years, I think this is absolutely critical 12 to have physicians that you can turn to and rely on to 13 tell you what the clinical unmet needs are in the 14 marketplace and what the issues are. They're the ones 15 that are dealing with their patients. They're the ones 16 that understand the issues, whether it be with our own 17 product or with the competitive product. 18 And our goal with these doctors is to work with 19 them, to understand those needs, and hopefully come up 20 with new devices. In addition to that, I mentioned the 21 training. It's a very important aspect of physicians 22 that we work with in helping us train as part of their 23 role. 24 And then also we have medical advisory boards.</p> <p style="text-align: center;">421</p> <p>1 We pull them together and talk about where the market is 2 going and what are the trends, et cetera. 3 Q. The next slide talks about programs. When you 4 are talking about programs in terms of marketing, give 5 the jury some sense for what that means. 6 A. Well, programs can fall in different areas. 7 For urology and women's health, an example of a most 8 recent program is the "Always There" program. 9 This is a program we put in place. It's a 10 program directed to the physicians. And so our goal in 11 this campaign is to tell our physicians that we are</p>	<p>421:3- 421:20 FRE 401, 402, 403</p>	
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<p>12 committed to our pelvic organ prolapse line, that we're</p> <p>13 committed to our stress urinary incontinence line, that</p> <p>14 we're committed to women's health, and we are going to</p> <p>15 remain committed to them, that area.</p> <p>16 It's been highly effective because we've been</p> <p>17 able to talk to physicians about clinical data. We've</p> <p>18 been able to have very frank conversations about the</p> <p>19 market and the PHNs and so on. And it's been a very</p> <p>20 effective program.</p> <p>21 Q. Finally, you talk about people. Tell the jury</p> <p>22 what role people play in Boston Scientific's success.</p> <p>23 A. Well, I think internally in an organization it</p> <p>24 all starts with the people. You have to have the right</p> <p style="text-align: center;">422</p> <p>1 people in an organization that have the right skills,</p> <p>2 the competencies, the talent, and also that will always</p> <p>3 do the right thing.</p> <p>4 And that's something I've taken a lot of pride</p> <p>5 in, in developing people, hiring people. It's something</p> <p>6 that I think I'm pretty good at identifying individuals</p> <p>7 that can help us improve and get better as a company.</p> <p>8 And I'm a big believer in developing these people and</p> <p>9 moving forward.</p>		
<p>eb082313, (Pages 423:21 to 425:15)</p> <p style="text-align: center;">423</p> <p>21 Q. One of the innovative features of the Pinnacle</p> <p>22 and Uphold devices that you mentioned was use of the</p> <p>23 Capiro device instead of trocars.</p> <p>24 What was the benefit of having the -- using the</p> <p style="text-align: center;">424</p>	<p>423:21-424:12 FRE 401, 402, 403, 701, 702, 801, and 802</p>	

<p>1 Capiro suturing device instead of using trocars?</p> <p>2 A. So again, I want to reiterate. This came from</p> <p>3 the physician community that came back to us as we were</p> <p>4 looking at getting into the pelvic organ prolapse. We</p> <p>5 were already in the stress urinary incontinence</p> <p>6 business. And what the physicians came to us and said</p> <p>7 we need to figure out a way to do this procedure</p> <p>8 intravaginally so we do not have to go through the</p> <p>9 buttocks, we do not have to have a blind pass with</p> <p>10 trocars, and we can have a way to get Level 1 support to</p> <p>11 simplify the procedure and get better outcomes for the</p> <p>12 patient. That's what it was about.</p> <p>13 Q. And the plaintiffs' lawyers asked you</p> <p>14 specifically about one sentence in this document that</p> <p>15 talks about "Our Number 1 goal is to outsmart our</p> <p>16 competitors and take share!"</p> <p>17 Do you see that?</p> <p>18 A. Yes. Sorry. I see it now.</p> <p>19 Q. Can you read the next sentence after that for</p> <p>20 me, please.</p> <p>21 A. Yeah. The next sentence says, "It is all about</p> <p>22 building solutions for your customers that are better</p> <p>23 than the solutions our competitors can provide."</p> <p>24 Q. And in terms of solutions, when you're talking</p> <p style="text-align: center;">425</p> <p>1 about that, what are the aspects of solutions that make</p> <p>2 good products for physicians?</p> <p>3 A. Well, I'll use the example of, again, Pinnacle</p> <p>4 or Uphold. I can list devices on the urology side where</p> <p>5 if there's a clinical unmet need and the doc says we</p>		
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<p>6 need this, they're basically saying we need a solution</p> <p>7 to this given problem, this clinical issue that's either</p> <p>8 impacting the way I do the procedure or impacting the</p> <p>9 end result to my patient where I want a better outcome</p> <p>10 for my patient.</p> <p>11 So when we talk about solutions and we talk</p> <p>12 about bringing our products to the market, we're talking</p> <p>13 about responding to what the customer is asking for and</p> <p>14 ensuring that what we're doing does improve patient</p> <p>15 lives.</p>		
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1. Counter Exhibits to Counter Exhibits
a. Brasington 610

DATED: July 20, 2015

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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